Appendix 1

JUL 2 6 2013

510(k) Summary

K130680
510(k) Summary Pursuant to 21 CFR 807.92

General Company Information

Company Name:	Dentsoll, Inc.
Company Address:	5836 Buford Hwy. #A, Norcross, GA 30071
Company Telephone:	770-314-5226
Contact:	David C. Furr, MS FDC Services, LLC
Contact Address:	8708 Capehart Cove Austin, Texas 78733 (512) 906-9654
Date:	May 8, 2013
Device Trade Names:	ACRYTONE, REZEN NF, and ISO FAST denture resins
Classification Name and Reference:	Resin, Denture, Relining, Repairing, Rebasing Product Code EBI 21 CFR§872.3760
Predicate Devices:	PalaXpress ultra Heraeus Kulzer, LLC K110037, Cleared 04/29/2011

	DEFLEX NUXEN S.R.L. K113608, Cleared 04/10/2012
Device Description:	Dentsoll High Dental Denture Resins are acrylic and polyamide resins for use in creating, relining, repairing, and rebasing denture bases. They are available in clear or pink colors. The Rezen NF and Acrytone resin granules can be used for injection molding and the ISO FAST self curing resin is mixed and applied as a liquid for repairs.
Intended Use:	Dentsoll High Dental Denture Resins are intended for manufacturing, relining, repairing, and rebasing of partial or full removable dentures, dental plates, bite plates, personal trays, appliances, occlusal splints and night guards.
Performance Data: **(Nonclinical and/or Clinical):**	The results of non-clinical testing demonstrated that the devices are safe and effective. Device testing of the Dentsoll High Dental Denture Resins was conducted in accordance with ISO ISO 20795-1 *Denture Base Polymers*. Testing included physical appearance, surface property, hue stability, transparency, presence of air bubbles, flexural strength, flexural elasticity, bonding strength with a dental implant, presence of residuals, water sorption, and solubility.
Biocompatibility:	Dentsoll High Dental Denture Resins are formed into surface contacting dental

	devices with limited (less than 24 hours) contact duration. Biocompatibility of the resins was analyzed in accordance with ISO 10993. Testing included the following: ISO 10993-5 Cytotoxicity - pass ISO 10993-10 Sensitization - pass ISO 10993-11 Systemic Toxicity - pass
Conclusion:	There are no significant differences between the Dentsoll High Dental Denture Resins and the predicate devices. All devices are tested to meet ISO 20795 and ISO 10993. Formulations, presentation, and colors are very similar. The devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Dentsoll, Incorporated
C/O Mr. David C. Furr, MS
FDC Services, Limited Liability Company
8708 Capehart Cove
Austin, Texas 78733

Re: K130680
Trade/Device Name: Dentsoll – High Dental Denture Resins
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: March 12, 2013
Received: May 14, 2013

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130680

Device Name: Dentsoll – High Dental Denture Resins

Indications For Use:

Dentsoll High Dental Denture Resins are intended for manufacturing, relining, repairing, and rebasing of partial or full removable dentures, dental plates, bite plates, personal trays, appliances, occlusal splints and night guards.

Prescription Use X or Over-the-counter use
(per CFR 801.109)

Concurrence of CDRH

Sheena A. Green -S
2013.07.26 11:38:56 -04'00'
for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130680